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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,691	01/22/2002	Xuanchuan (Sean) Yu	LEX-0303-USA	5177

7590 01/21/2004

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EXAMINER	
NASHED, NASHAAT T	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,691	YU ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed	1652	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/20/02 &* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-4 are pending and under consideration.

The abstract of the disclosure is objected to because it does not describe the claimed invention. Correction is required. See MPEP § 608.01(b).

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose the nucleic acid of SEQ ID NO: 1 which encodes the polypeptide of SEQ ID NO: 2. Based on a reasonable sequence homology with a known lipase, the polypeptide of SEQ ID NO: 2 is sought to be a lipase which is a non-specific asserted utility. Lipase is a class of enzymes which catalyze the hydrolysis of many lipids having different structure and functions. Thus, each lipid is expected to have a specific substrate(s) and function. The specification does not specifically disclose a specific function of the polypeptide of SEQ ID NO: 2, its relationship to any disease, or any specific real world use. The specification describe non-specific functions for the protein, nucleic acid, and antibodies. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantly make the polypeptide of SEQ ID NO: 2 which neither the gene or the polypeptide associated with a specific use or a disease. The mere fact that the polypeptides disclosed in the specification are called collectively novel human lipase (NHL) is indicative that the applicants have no idea about the specific function of these proteins at the time they filed their application. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 2, it is directed to all possible nucleic acid sequences that hybridizes to SEQ ID NO: 1 under any stringent conditions regardless of their function. The specification, however, only provides representative species of these nucleic acid sequences from human encoding a proteins that is asserted to be a lipase without identifying the actual function of the protein. Moreover, the specification fails to describe additional representative species of these nucleic acid sequences by any identifying structural characteristics or properties other than they encode polypeptides such as that of SEQ ID NO: 2. Since the specification lacks teaching of the function of the polypeptides and/or a structure function relationship, the specification fails to impart a high predictability of structure for any additional lipases. Given this lack of additional representative species as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "stringent conditions" renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent

protection desired. Since there are several hybridization conditions known in the art as "stringent conditions" and the result of a hybridization experiment will vary with each set of "stringent conditions", the claim is found indefinite. It is noted that the specification exemplifies a stringent hybridization conditions, see page 4, lines 30-34. Stating the hybridization conditions on page 4, lines 30-34 in the claim would overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Boll *et al.* (IDS: reference CH: J. Biol. Chem. 1993, 268 (17), 12901-12911).

Boll *et al.* teach a nucleic acid encoding a polypeptide having esterase and phospholipase A/lysophospholipase activity, see the abstract and Figure 3. The nucleic acid sequence of SEQ ID NO: 1 of the instant application is 71.4% homologous to the nucleic acid sequence taught by Boll *et al.* Thus, the nucleic acid sequence of the instant application is expected to hybridize to SEQ ID NO: 1 under some stringent conditions.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Zhu (IDS: reference CQ: WO200231161).

Zhu teaches the human nucleic acid sequence of SEQ ID NO: 1 encoding the polypeptide SEQ ID NO: 2 which is described as lipase-like polypeptide, see the sequence listing. The nucleic acid sequence of SEQ ID NO: 1 of the instant application is 79.1% homologous to the nucleic acid sequence taught by Zhu with best local homology of 97.5%

over residues 775-4365 of SEQ ID NO: 1 of the instant application. Thus, the nucleic acid sequence of the instant application is expected to hybridize to SEQ ID NO: 1 under any stringent conditions.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m. The examiner is expected to move to the new Patent and Trademark Office facility in Alexandria, VA on January 22, 2004. The new telephone number for the examiner will be 571-272-0934.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph. D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401. Effective January 22, 2004 Dr. Achutamurthy telephone number will be 571-272-0928.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner